REMARKS

Applicants have carefully considered this Application in connection with the Examiner's Action, and respectfully request reconsideration of this Application in view of the above Amendment and the following remarks.

Applicants have cancelled claims 24 and 28. Pending in this Application are Claims 1 – 23, 25 – 27, and 29 – 31.

I. Rejections for Double Patenting

Claims 1 – 23, 25 – 27, and 29 – 31 stand rejected under the judicially created doctrine of double patenting with regard to U.S. Patent No. 6,274,177 ("the '177 Patent").

Applicants have amended all pending claims to recite a method of treating a disease associated with *Trichophyton mentagrophytes* or *Pityrosporum ovale* by applying topically the anti-fungal pharmaceutical composition disclosed. The '177 Patent does not contain claims directed to this method of treatment. Thus, the current application and the '177 Patent are patentably distinct. In light of this, Applicants respectfully request that the rejections for double patenting be withdrawn.

II. Rejections Under 35 U.S.C. §102(b)/103(a)

Claims 1 – 23, 25 – 27, and 29 – 31 stand rejected under 35 U.S.C. §102(b) or 35 U.S.C. §103(a) as anticipated by or obvious in light of Kasuya et al., Tsumura & Co. JP02004711, Weidner DK 9700132, or U.S. Patent No. 6,264,928 to Jean et al. Applicants assert that, in light of the above Amendment, the current claims are not anticipated or obvious in light of any of the references. None of the references listed discloses or suggests using the pharmaceutical composition to treat diseases associated with *Trichophyton mentagrophytes* or *Pityrosporum ovale*. Thus, Claims 1 – 23, 25 – 27, and 29 – 31 are not anticipated and would not have been

obvious in light of these references. Applicants respectfully request that the rejections under 35 U.S.C. §102(b) and 35 U.S.C. §103(a) be withdrawn.

III. **Conclusion**

Applicants respectfully submit that, in light of the foregoing Amendments and comments, Claims 1 – 23, 25 – 27, and 29 – 31 are in condition for allowance. A Notice of Allowance is therefore requested.

If the Examiner has any other matters which pertain to this Application, the Examiner is encouraged to contact the undersigned to resolve these matters by Examiner's Amendment where possible.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Please amend Claims 1 – 23 as follows:

1. [An] A method of treating a patient suffering a disease associated with *Trichophyton mentagrophytes* or *Pityrosporum ovale* by applying topically an anti-fungal pharmaceutical composition comprising a therapeutically effective amount of a product prepared from rhizomes of *Zingiber officinale*, as an active ingredient, in admixture with a pharmaceutically acceptable carrier or diluent for the active ingredient, wherein said product is prepared by the following steps:

a) preparing a crude liquid from rhizomes of *Zingiber officinale*;

b) introducing the crude liquid to a reverse phase chromatography column, and eluting the column with water, a first eluent and a second eluent in sequence, said second eluent having a polarity weaker than that of the first eluent but stronger than that of chloroform, so that a first eluate resulting from elution of the first eluent and a second eluate resulting from elution of the second eluent are obtained;

c) removing the first eluent from the first eluate by evaporation, so that a first concentrated eluate is obtained and is able to be used as the product; and

d) removing the second eluent from the second eluate by evaporation, so that a second concentrated eluate is obtained and is able to used as the product;

wherein step a) comprises steps i) to iv), or comprises step I), step I'), or step I"), wherein said steps i) to iv) are:

i) shedding fresh rhizomes of *Zingiber officinale* and filtering the resulting mixture to obtain a filtrate and a residue;

ii) extracting the filtrate with a first organic solvent, recovering the resulting extraction solution of the first organic solvent, and evaporating the first organic solvent from the extraction solution to obtain a first concentrated extraction solution;

iii) extracting the residue with a second organic solvent, recovering the resulting extraction solution of the second organic solvent, and evaporating the second organic solvent from the extraction solution to obtain a second concentrated extraction solution; and

iv) combining the first concentrated extraction solution and the second concentrated extraction solution to obtain the crude liquid;

said step I) is:

I) extracting powder of dried rhizomes of *Zingiber officinale* with the second organic solvent, recovering the resulting extraction solution of the second organic solvent, and evaporating the second organic solvent from the extraction solution to obtain the crude liquid;

said step I') is:

I') steam distilling powder of dried rhizomes of *Zingiber officinale*, and concentrating the resulting distillate by evaporation to obtain the crude liquid; and

said step I") is:

I") extracting powder of dried rhizomes of *Zingiber officinale* with supercritical CO_2, recovering the resulting extraction solution of the supercritical CO_2, and evaporating CO_2 from the extraction solution to obtain the crude liquid.

2. The [pharmaceutical composition] <u>method</u> according to claim 1, wherein the product as the active ingredient comprises 0 - 10 mg 6-shogaol per gram of the product, 1 - 150 mg 6-gingerol per gram of the product, and 0 - 40 mg 6-dehydrogingerdione per gram of the product.

3. The [pharmaceutical composition] <u>method</u> according to claim 1, wherein said first eluent is methanol, and said second eluent is acetone

4. The [pharmaceutical composition] method according to claim 3, wherein step a) comprises steps i) to iv).

5. The [pharmaceutical composition] method according to claim 4, wherein said first organic solvent is ethyl ether.

6. The [pharmaceutical composition] method according to claim 4, wherein said second organic solvent is acetone, methanol, ethanol or a combination of them.

7. The [pharmaceutical composition] method according to claim 6, wherein said second organic solvent is acetone.

8. The [pharmaceutical composition] method according to claim 3, wherein step a) comprises step I).

9. The [pharmaceutical composition] method according to claim 8, wherein said second organic solvent is acetone, methanol, ethanol or a combination of them.

10. The [pharmaceutical composition] method according to claim 9, wherein said second organic solvent is acetone.

11. The [pharmaceutical composition] method according to claim 3, wherein step a) comprises step I').

12. The [pharmaceutical composition] method according to claim 3, wherein step a) comprises step I").

13. The [pharmaceutical composition] method according to claim 1, wherein said reverse phase chromatography column is packed with a porous resin.

14. [An] A method of treating a patient suffering a disease associated with *Trichophyton mentagrophytes* or *Pityrosporum ovale* by applying topically an anti-fungal pharmaceutical composition comprising a therapeutically effective amount of [the] a crude liquid prepared [according to step a) in

claim 1] from rhizomes of *Zingiber officinale* , as an active ingredient, in admixture with a pharmaceutically acceptable carrier or diluent for the active ingredient,

wherein said crude liquid is prepared by a process comprising steps i) to iv), or comprising step I), step I'), or step I"), wherein said steps i) to iv) are:

i) shedding fresh rhizomes of *Zingiber officinale* and filtering the resulting mixture to obtain a filtrate and a residue;

ii) extracting the filtrate with a first organic solvent, recovering the resulting extraction solution of the first organic solvent, and evaporating the first organic solvent from the extraction solution to obtain a first concentrated extraction solution;

iii) extracting the residue with a second organic solvent, recovering the resulting extraction solution of the second organic solvent, and evaporating the second organic solvent from the extraction solution to obtain a second concentrated extraction solution; and

iv) combining the first concentrated extraction solution and the second concentrated extraction solution to obtain the crude liquid;

said step I) is:

I) extracting powder of dried rhizomes of *Zingiber officinale* with the second organic solvent, recovering the resulting extraction solution of the second organic solvent, and evaporating the second organic solvent from the extraction solution to obtain the crude liquid;

said step I') is:

I') steam distilling powder of dried rhizomes of *Zingiber officinale*, and concentrating the resulting distillate by evaporation to obtain the crude liquid; and

said step I") is:

I") extracting powder of dried rhizomes of *Zingiber officinale* with supercritical CO_2, recovering the resulting extraction solution of the supercritical CO_2, and evaporating CO_2 from the extraction solution to obtain the crude liquid.

15. The [pharmaceutical composition] method according to claim 14, wherein said process comprises steps i) to iv).

16. The [pharmaceutical composition] method according to claim 15, wherein said first organic solvent is ethyl ether.

17. The [pharmaceutical composition] method according to claim 16, wherein said second organic solvent is acetone, methanol, ethanol or a combination of them.

18. The [pharmaceutical composition] method according to claim 17, wherein said second organic solvent is acetone.

19. The [pharmaceutical composition] method according to claim 14, wherein said process comprises step I).

20. The [pharmaceutical composition] method according to claim 19, wherein said second organic solvent is acetone, methanol, ethanol or a combination of them.

21. The [pharmaceutical composition] method according to claim 20, wherein said second organic solvent is acetone.

22. The [pharmaceutical composition] method according to claim 14, wherein said process comprises step I').

23. The [pharmaceutical composition] method according to claim 14, wherein said process comprises step I").

Please cancel Claim 24.

Please amend Claims 25 – 27 as follows:

25. The [pharmaceutical composition] method according to claim [24] 1, in which said disease is selected from the group consisting of tinea pedis, tinea capitis, tinea cruris, tinea glabrosa, onychomycosis, pityriasis capitis, pityriasis vesicolor, pityrosporum folliculitis, seborrheic dermatitis and dandruff.

26. The [pharmaceutical composition] method according to claim [24] 1, which is in the form of a shampoo, a bath gel, soap, a body lotion, a body cream or a detergent.

27. The [pharmaceutical composition] method according to claim 26, which is in the form of a shampoo for use in the treatment of dandruff.

Please cancel Claim 28.

Please amend Claims 29 – 31 as follows:

29. The [pharmaceutical composition] method according to claim [28] 14, in which said disease is selected from the group consisting of tinea pedis, tinea capitis, tinea cruris, tinea glabrosa, onychomycosis, pityriasis capitis, pityriasis vesicolor, pityrosporum folliculitis, seborrheic dermatitis and dandruff.

30. The [pharmaceutical composition] method according to claim [28] 14, which is in the form of a shampoo, a bath gel, soap, a body lotion, a body cream or a detergent.

31. The [pharmaceutical composition] method according to claim 30, which is in the form of a shampoo for use in the treatment of dandruff.